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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,827	07/31/2001	Richard K. Haynes	LEA 33 820	8606
35969	7590	05/10/2004	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516			WRIGHT, SONYA N	
		ART UNIT	PAPER NUMBER	
		1626		

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,827	HAYNES ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16,23 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 16,23 and 28-34 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2-11-04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

This Action is in response to Applicant's amendment filed February 11, 2004.

Claims 16, 23, and 28-34 are pending in this application.

The elected subject matter of this application pertains to compounds, compositions and processes relating to formula I wherein Y is represented by a C-linked heteroaryl or heterocyclalkyl group, or a group NR1R2 wherein R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted heterocyclic group. Applicant's amendment has deleted subject matter in the claims wherein Y is represented by a C-linked heteroaryl or heterocyclalkyl group. Applicant's amendment has limited the claims to wherein Y is represented by a group NR1R2 wherein R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted heterocyclic group.

The rejections in the previous office action and the objection to claims for containing non-elected subject matter have been overcome with Applicant's amendment. Upon further consideration, the following new grounds of rejection are made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Claims 16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1122806, Li et al, (STN International ® 1999:234337; RN 221890-88-6 and RN 221890-90-0, Abstract).

RN 221890-88-6 anticipates the instant compound when, in the instant compounds, Y is –NR1R2 wherein R1 and R2 together with the interjacent nitrogen atom represent 9H-purin-6-amine.

RN 221890-90-0 anticipated the instant compound when, in the instant compounds, Y is –NR1R2 wherein R1 and R2 together with the interjacent nitrogen atom represent 1H-1,2,4-triazole-3-carboxamide.

The abstract in STN International discloses that the compound of Li et al. is useful in antitumor agents.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted non-aromatic heterocyclic group. However, it is unclear what substituents may appear on the heterocyclic group. For example, the elected species, Example 7, contains two oxo groups on the sulfur in the thiomorpholine ring. However, the term “oxo” does not appear in the list of substituents on page 11, lines 17-23.

Clarification is requested regarding whether dioxothiomorpholine is the only compound intended to have oxo groups as substituents on the heterocyclic group.

Claim 28 is rejected for being dependent on rejected claim 16.

Response to Arguments

Applicant's arguments, filed 2-11-04 have been considered. Applicant's amendments have overcome the rejection(s) of claim(s) 16 and 23 under 35 U.S.C. 102(b) and the objections to claims for containing non-elected subject matter from the previous office action. However, upon further consideration, a new ground(s) of rejection is made. See the rejections under 35 U.S.C. 102 and 35 U.S.C. 112 (supra).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (571) 272-0711. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The Official fax phone number for this Group is (703) 872-9306.

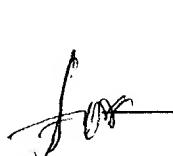
When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the

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applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to Technology Center 1600 at (571) 272-1600.

Joseph K. McKane
Supervisory Patent Examiner
Group 1600

Sonya Wright

April 30, 2004